

bonded to SV by hydrophobic interactions, while OH groups are oriented towards the outer side of the aggregate. Hence, the formed aggregate is more hydrophilic than SV molecule alone. **CONCLUSIONS:** Our data indicate that CA decreases the values of SV distribution coefficient. This may be the result of the formation of hydrophilic complexes increasing the solubility of SV that could consequently lead to the increase of SV bioavailability. In order to confirm these results, further in vivo investigations of their interactions at molecular level need to be undertaken. Acknowledgement: This work is supported by Ministry of Education, Science and Technological Development of Serbia, Project III41012.

PRM17

COMPARISON OF CHRONIC HEPATITIS C TREATMENT EFFICACY IN RANDOMIZED CONTROLLED TRIALS AND REAL-LIFE STUDIES - INFLUENCE OF STUDY DESIGN IN THE SUSTAINED VIROLOGICAL RESPONSE: A SYSTEMATIC REVIEW OF PUBLISHED LITERATURE

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OBJECTIVES: To assess whether hepatitis C treatment outcome was similar among different study designs. **METHODS:** Two independent reviewers conducted a double-screened systematic review on hepatitis C treatment. Studies were categorized under study design: randomized controlled trials (RCT), pragmatic trials (PRG) and registries; and treatment course: pegylated interferon and ribavirin (IR), IR and boceprevir (BCP), IR and telaprevir (TLP). 3,713 abstracts were retrieved, and 253 studies were included according to previously selected criteria, comprising 77,042 patients. Sustained virological response (SVR) was established as treatment end-point. Mann-Whitney-U and Kruskal-Wallis tests were used with a 95% CI. **RESULTS:** In the IR group, registries had a lower SVR than PRG ($P=0.039$) and than RCT ($P=0.3368$). RCT had a worse outcome than PRG ($P=0.283$). Statistical difference was seen among the three BCP groups ($P=0.040$), and RCT had a higher SVR than registries ($P=0.028$). BCP PRG group couldn't be analysed in comparison to other study designs due to a very small group. PRG (SVR=80.13%) had a better outcome than RCT (SVR=75.00%) and than registries (SVR=62.00%), but tests have shown no statistical significance among study designs ($P>0.05$). **CONCLUSIONS:** It's possible to design close to the real-life settings RCT. Though it's not a rule, each drug should be studied separately and its clinical scenario considered. PRG might be not as pragmatic as they claim to be, as their results were more similar to RCT than to registries. Further analysis should assess whether PRG are fully bridging RCT's gap to the real-life settings, as they are intent to be the main guide to drug's embodiment to the clinical practice. Also, boceprevir was less studied than telaprevir, and whether remains unclear which drug is more effective, new data could answer that, specially a large proportions head-to-head RCT comparing both drugs. Although, as of new and better treatment courses are approved, this RCT most probably will not be done.

RESEARCH ON METHODS – Conceptual Papers

PRM18

ENGAGING HISPANIC CAREGIVERS IN RESEARCH: A FRAMEWORK TO DESIGN CULTURALLY SENSITIVE APPROACHES FOR ENGAGEMENT IN PATIENT-CENTERED OUTCOMES RESEARCH

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The Latin American perspective on caregivers' preferences is underrepresented in research largely due to lack of culturally sensitive approaches to enhance research literacy. Identification of the most effective engagement strategies is needed so that patient centered outcomes research (PCOR) can address the needs and priorities of caregivers of Latin American origin. Our objectives were to develop a methodological framework for engaging caregivers of Latin American origin in research and to improve PCOR literacy in this population. The 'pre-engagement' framework with hard-to-reach patients was used in a study designed to identify caregivers' priorities for treatment and outcomes in children of Hispanic origin living in the U.S. with complex mental health conditions. Based on the principles of community based participatory research, the pre-engagement implementation phases were: 1. Identify Hispanic community leaders with common goals; 2. Partner with leaders to select key topics of interest; 3. Design culturally appropriate strategies; 4. Implement pre-engagement strategies. During phase 1, academic partnerships were developed with community leaders to allow integration into the research process. Community needs and practical challenges to engage caregivers and the strategies to overcome barriers were identified during phase 2. In phase 3, a series of four workshops, delivered in Spanish, were designed as interactive activities each addressing a unique challenge: understanding the caregiver's perspective, understanding the child's perspective, providing behavior management strategies, and discussing community resources for families. Each workshop emphasized research literacy by linking the benefit of research in advancing the challenge being discussed. An outcome of this work will be a caregiver resource guide in Spanish, developed by Hispanic community leaders, for distribution in their communities. In the absence of culturally appropriate tools to address health and medical preferences of non-English speaking communities, this framework can be used to engage caregivers and communities in patient-centered research.

PRM19

O MÉTODO PARACONSISTENTE COMO SUPORTE ÀS TOMADAS DE DECISÃO EM SAÚDE

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INTRODUÇÃO: O presente estudo objetiva apresentar a Lógica Paraconsistente Anotada Evidencial (LPAE), que é a base teórica para o modelo proposto de suporte

às tomadas de decisão em saúde. **DESENVOLVIMENTO:** A Lógica Paraconsistente é uma opção metodológica que permite manipular dados imprecisos, inconsistentes e paracompletos. A aplicação do método consiste basicamente de oito etapas: 1-fixar o nível de exigência da decisão que se pretende tomar; 2-selecionar os fatores mais importantes e de maior influência na decisão; 3-estabelecer as seções para cada um dos fatores; 4-construir a base de dados que é constituída pelos pesos atribuídos aos fatores e pelos valores de evidência favorável e de evidência contrária atribuídos a cada um dos fatores em cada uma das seções (os pesos e os valores das evidências são atribuídos por especialistas selecionados para o estudo); 5-fazer a pesquisa de campo para verificar, no caso em análise, em que seção (condição) cada um dos fatores se encontra; 6-obter o valor da evidência favorável e o valor da evidência contrária resultantes para cada um dos fatores escolhidos, por meio da aplicação das técnicas de maximização e minimização da LPAE; 7- obter o grau de evidência favorável e o grau de evidência contrária do baricentro dos pontos que representam os fatores escolhidos no reticulado paraconsistente; 8-tomar a decisão, aplicando-se a regra de decisão ou algoritmo para-analisador. **CONCLUSÃO:** Em situações em que a tomada de decisão precisa ser realizada em curto período de tempo, transferir e adaptar avaliações econômicas realizadas em outros contextos pode ser uma necessidade considerável. O método paraconsistente pode contribuir nesse processo, apoiando o trabalho das comissões hospitalares de avaliação e incorporação de tecnologias em saúde.

DISEASE – SPECIFIC STUDIES

CANCER – Clinical Outcomes Studies

PCN1

PHARMACOVIGILANCE IN ONCOLOGY: KNOWLEDGE AND PERCEPTION ON ADVERSE EVENTS REPORTING IN BRAZIL

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OBJECTIVES: Pharmacovigilance represents an important tool to support the maintenance of drug safety through evaluation of spontaneous adverse events (AE) reporting. AEs represent one important cause of morbidity and mortality worldwide when not managed correctly, being very frequent, especially during oncology treatments. However, underreported phenomenon occurs often due inefficient spontaneous reporting by patients, physicians and caregivers. Therefore, the aim of this survey was to evaluate the knowledge and perception related to pharmacovigilance in Brazil. **METHODS:** From February to March 2015, 260 respondents answered an internet-based survey related to knowledge on pharmacovigilance from Oncoguia Institute, an independent nonprofit cancer advocacy institution. Descriptive analyses were performed according to answers frequency. **RESULTS:** Among the respondents, 70.8% were diagnosed with cancer, of which breast cancer was the most frequent (58%) followed by colorectal cancer (4%). Reported treatment included chemotherapy (96%), surgery (84%), 48% radiotherapy (48%). Of all, 46% and 44% were treated by public and private health insurance, respectively. Most of the respondents were not aware of the importance of a pharmacovigilance AE report (52%). In fact, 21% of the respondents were not aware of what AEs are. In 66% of the cases, physicians have described the main AE expected to the prescribed treatment. Respondents reported nausea (80%), hair loss (77%), weight gain (49%) and vomiting (45%) as the most common AEs. Only 7% and 4% of the respondents were aware that AEs could be reported to pharmaceutical industry and ANVISA, respectively. **CONCLUSIONS:** This survey demonstrates that knowledge and perception regarding AEs, such as definition, importance and how to proceed in case of having one, including the importance of pharmacovigilance system, are very reduced among common public, including cancer patients. Therefore, there is an enormous need for educational intervention regarding AEs reporting importance in general public, patients and physicians, especially in oncology.

PCN2

EFICACIA Y SEGURIDAD DEL USO DEL CETUXIMAB EN PACIENTES CON CANCER COLORRECTAL METASTÁSICO

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OBJECTIVOS: Determinar la eficacia y seguridad de Cetuximab solo o asociado a otros fármacos en el tratamiento del cáncer colo-rectal metastásico comparado a los tratamientos actualmente disponibles. **METODOLOGÍAS:** Se realizó una búsqueda bibliográfica de revisiones sistemáticas y Ensayos Clínicos Aleatorizados (ECAS) en bases electrónicas Cochrane, Pubmed y Lilacs, que compararan ramas de tratamiento con y sin Cetuximab. **RESULTADOS:** Se seleccionaron 2 revisiones sistemáticas y 8 ECAS. Los resultados para los puntos finales de eficacia y seguridad en la población general fueron: Sobrevida Global (SG) HR 0,97 [0,89-1,05], Sobrevida Libre de Progresión (SLP) HR 0,84 [0,70-0,98], eventos adversos (EA) grado 3-4 HR 2,15 [1,88-2,45] y reacciones de piel 44,5 [22,1-89,5]. En la población KRAS wild la SG fue HR 0,796 IC95% [0,670-0,946] en el estudio de Van Cutsem, HR, 0,855 IC95% [0,599-1,219] en el estudio de Bokemeyer, 1,04 IC95% [0,87-1,23] en el estudio de Maughan y HR 0,55 IC95% [0,41-0,74] en el estudio de Jonker. Para la SLP en población KRAS wild los resultados fueron HR 0,57 IC95% [0,38-0,86] en el estudio de Bokemeyer, HR 0,40 IC95% [0,30-0,53] en el estudio de Jonker, HR 0,96 IC96% [0,82-1,12] en el estudio de Maughan y HR 0,70 IC95% [0,56-0,87] en el estudio de Van Cutsem. **CONCLUSIONES:** Los resultados analizados muestran un incremento en la SG en pacientes con KRAS wild y de la SLP. También se constata un incremento en la ocurrencia de EA graves. Considerando los resultados de eficacia y seguridad para Cetuximab, se recomienda realizar un estudio de costo-efectividad para decidir su posible inclusión en el FTM. En este sentido, no debe darse por concluida la evaluación hasta contar con dicha información.